

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

PCT

To:

see form PCT/ISA/220

WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)

Date of mailing
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference
see form PCT/ISA/220

FOR FURTHER ACTION
See paragraph 2 below

International application No.
PCT/GB2004/001812

International filing date (day/month/year)
29.04.2004

Priority date (day/month/year)
01.05.2003

International Patent Classification (IPC) or both national classification and IPC
A61K31/397, A61P43/00, A61P25/18, A61P25/28, A61P25/00, A61P1/00, A61P25/34, A61P3/04, A61P3/10

Applicant
VERNALIS RESEARCH LIMITED

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY

J005 Rec'd PCT/PTO 12 OCT 2005

International application No.
PCT/GB2004/001812

10/552574

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.
 - ☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
 - a. type of material:
 - ☐ a sequence listing
 - ☐ table(s) related to the sequence listing
 - b. format of material:
 - ☐ in written format
 - ☐ in computer readable form
 - c. time of filing/furnishing:
 - ☐ contained in the international application as filed.
 - ☐ filed together with the international application in computer readable form.
 - ☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

Box No. II Priority

1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
☒ claims Nos. 9-13 with respect to industrial applicability

because:

- ☒ the said international application, or the said claims Nos. 9-13 with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (*specify*):

see separate sheet

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
- | | |
|----------------------------|--|
| the written form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
| the computer readable form | <input type="checkbox"/> has not been furnished |
| | <input type="checkbox"/> does not comply with the standard |
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

Re Item III.

Claims 9 and 10-13 (as far as related to the method) relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1 (iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

Re Item V.

- 1 The following documents are referred to in this communication:

D1 : WO 99/37612 A (BODKIN CORINNA DAGMAR ; CEREBRUS LTD (GB);
ADAMS DAVID REGINALD (GB);) 29 July 1999 (1999-07-29)

D2: FR-A-2 805 817 (AVENTIS PHARMA SA) 7 September 2001 (2001-09-07)

D3: FR-A-2 805 810 (AVENTIS PHARMA SA) 7 September 2001 (2001-09-07)

- 2 The present application does not meet the criteria of Article 33(1) PCT, because the subject-matter of claims 1-9 is not new in the sense of Article 33(2) PCT. Document D1 discloses the use of the azetidinecarboxamide derivatives of formula (I) for the manufacture of a medicament for the treatment of anxiety, epilepsy, insomnia, senile dementia and alcohol withdrawal syndrome. All those diseases are disorders mediated by CB1 receptors (see D2 and D3).
- 3 The combination of the features of dependent claims 10-13 are neither known from, nor rendered obvious by, the available prior art. Consequently the subject-matter of claims 10-13 meets the requirements of Articles 33(2) and 33(3) PCT.
- 3.1. None of the cited documents discloses the use of the azetidinecarboxamide derivatives of formula (I) for the manufacture of a medicament for the treatment of psychosis, schizophrenia, cognitive disorders, attention deficit disorder, gastrointestinal disorders, smoking cessation, obesity and non-insulin dependant diabetes mellitus.

- 3.2 In the light of the prior art, the problem to be solved can be regarded as how to provide compounds with antagonist and/or inverse agonist properties at the cannabinoid-1 (CB1) receptor in order to treat the diseases mentioned in claims 10-13.

No indications were found that would have led the skilled person to choose the azetidinecarboxamides of formula (I) to solve the problem posed, so an inventive step in the sense of Article 33(3) PCT is acknowledged.

- 4 There are no doubts about industrial applicability for the subject-matter of claims 1-8 (Article 33(4) PCT).

- 4.1. For the assessment of the present claims 9-13 (as far as related to the method) on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.